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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,432	01/22/2002	Joshua Labaer	00246-260001/111803	7954

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/055,432	LABAER
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Sep 8, 2003*.

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-95* is/are pending in the application.

4a) Of the above, claim(s) *1-6, 8-47, 66-71, and 74-87* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *7, 48-65, 72, 73, and 88-95* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *303,090*
4) [ ] Interview Summary (PTO-413) Paper No(s). ____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [X] Other: *Detailed Action*

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group II, corresponding to claims 7, 48-65, 72-73, and 88-95 in Paper No. 1003 (dated September 8, 2003) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claim 7, 48-65 and 88-91 are rejected under 35 U.S.C. 103(a) over Schultz (PCT International Application number WO 90/05785) (May 31, 1990) in view of Wagner et al. (U.S. Patent 6,406,921 B1) (June 18, 2002).

Schultz teaches a method comprising:

a) providing a substrate that comprises address, each address comprising (I) a nucleic acid encoding a hybrid amino acid sequence comprising a test amino acid sequence and (ii) a binding agent;

b) contacting each address with a translation effector to thereby translate the hybrid amino acid sequence; and

c) maintaining the substrate under conditions permissive for the hybrid amino acid sequence to bind the binding agent (Abstract and Page 13, lines 5-26 and page 20, lines 3-11 and page 26, lines 3-36 and Figure 1 and Claims 1-8 and EXPERIMENTAL Section).

Schultz teaches a method further comprising contacting cells or members of a display library to the substrate and evaluating the cells or a parameter of the cells (Claim 3).

Schultz teaches a method, wherein the test amino acid sequences comprise naturally occurring sequences (EXPERIMENTAL Section).

Schultz teaches a method, wherein the test amino acid sequences comprise bacterial antigens (Page 21, lines 4-14 and page 35, first paragraph).

Schultz teaches a method, wherein nucleic acid comprises plasmid DNA (Figure 1).

Schultz does not teach a plurality of addresses comprising binding agent that recognizes the affinity tag.

Wagner et al. teach a plurality of addresses comprising binding agent that recognizes the affinity tag (Column 20, lines 58-67 and Figures 6-8).

Schultz does not teach a method further comprising contacting endoplasmic reticulum vesicles to the protein synthesizing system.

Wagner et al. teaches a method further comprising contacting endoplasmic reticulum vesicles to the protein synthesizing system (Column 15, lines 34-53).

Schultz does not teach a method further comprising contacting a patient sample to the substrate.

Wagner et al suggests a method further comprising contacting a patient sample to the substrate (Abstract). This suggestion is deduced from the fact that Wagner et al teaches that this method can be used in clinical diagnostics.

Schultz does not teach a method, wherein the test amino acid sequences at the plurality of addresses comprise allergens and/or auto-immune antigens or hepatitis viral antigens.

Wagner et al. teach a method, wherein the test amino acid sequences at the plurality of addresses comprise allergens and/or auto-immune antigens or hepatitis viral antigens (Column 7, lines 34-47).

Schultz does not teach a method, wherein the test amino acid sequences comprise transmembrane proteins whose transmembrane domains have been excised.

Wagner et al. teach a method, wherein the test amino acid sequences comprise transmembrane proteins whose transmembrane domains have been excised (Column 7, lines 34-47 and Column 14, lines 10-24).

Schultz does not teach a method, wherein the test amino acid sequences at the plurality of addresses comprise randomized amino acid sequences.

Wagner et al. teach a method, wherein the test amino acid sequences at the plurality of addresses comprise randomized amino acid sequences.(Column 7, lines 20-33).

Schultz does not teach a method, wherein the test amino acid sequence comprises an immunoglobulin variable domain.

Wagner et al. teach a method, wherein the test amino acid sequence comprises an immunoglobulin variable domain (Column 7, lines 34-47).

Schultz does not teach a method, wherein the substrate comprises at least 10 addresses per cm square.

Wagner et al. teach a method, wherein the substrate comprises at least 10 addresses per cm square.(Column 7, lines 3-10 and Figure 1).

Schultz does not teach a method further comprising evaluating the substrate for a fluorescence and using a mass spectroscopy and for an enzymatic property.

Wagner et al. teach a method further comprising evaluating the substrate for a fluorescence and using a mass spectroscopy and for an enzymatic property (Figure 9 and Column 17, lines 36-61 and Column 20, lines 65-67).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein a plurality of addresses comprising binding agent that recognizes the affinity tag of Wagner et al. in the method of Schultz since Wagner et al. states, "The protein-coated substrates and protein arrays are particularly useful in high-throughput drug screening and clinical diagnostics (Abstract, last sentence) ". Moreover, Schultz states, "Novel methods are provided for producing proteins, containing unnatural amino acids at specific sites. The methods can utilize modified aminoacyl tRNAs capable of polymerizing a desired unnatural amino acid at unique codons within an mRNA sequence (Abstract)". By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the method, wherein a plurality of addresses comprising binding agent that recognizes the affinity tag of Wagner et al. in the method of Schultz, in order to achieve the express advantages, as noted by Wagner et al., of protein-coated substrates and protein arrays, which are particularly useful in high-throughput drug screening and clinical diagnostics and also in order to achieve the express advantages, as noted by Schultz, of novel methods provided for producing proteins, containing unnatural amino acids at specific sites, which can utilize modified aminoacyl tRNAs capable of polymerizing a desired unnatural amino acid at unique codons within an mRNA sequence.

Schultz in view of Wagner et al do not teach the method, wherein each address contains less than 1 ng or 10 pg of the nucleic acid.

However, it is *prima facie* obvious that selection of the specific amount of nucleic acid in an array represents routine optimization with regard to the size and requirement of the bioactive agent to be assayed and also to the intensity of the signal of the binding complex to be studied, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the specific amount of nucleic acid selected in an array was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

4. Claims 72 and 73 are rejected under 35 U.S.C. 103(a) over Schultz (PCT International Application number WO 90/05785) (May 31, 1990) in view of Wagner et al. (U.S. Patent 6,406,921 B1) (June 18, 2002) further in view of Guegler et al. (U.S. Patent 6,420,150 B1) (July 16, 2002).

Schultz in view of Wagner et al. teach a method of claims 7, 48-65 and 88-91 as described above.

Schultz in view of Wagner et al. do not teach a method, wherein each address further comprises a varying amount of a nucleic acid encoding a modifying enzyme.

Guegler et al. teach a method, wherein each address further comprises a varying amount of a nucleic acid encoding a modifying enzyme (Abstract and Column 31, lines 11-64).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein each address further comprises a varying amount of a nucleic acid encoding a modifying enzyme of Guegler et al. in the method of Schultz in view of Wagner et al. since Guegler et al. states, "The present invention specifically provides novel drug-metabolizing peptides and proteins and nucleic acid molecules encoding such protein molecules for use in the development of human therapeutics and human therapeutic development (Column 1, lines 15-19) ". An ordinary practitioner would have been motivated to combine and substitute the method, wherein each address further comprises a varying amount of a nucleic acid encoding a modifying enzyme of Guegler et al. in the method of Schultz in view of Wagner et al., in order to achieve the express advantages, as noted by Guegler et al., of an invention, which specifically provides novel drug-metabolizing peptides and proteins and nucleic acid molecules encoding such protein molecules for use in the development of human therapeutics and human therapeutic development.

5. Claims 52 and 92-95 are rejected under 35 U.S.C. 103(a) over Schultz (PCT International Application number WO 90/05785) (May 31, 1990) in view of Wagner et al. (U.S. Patent

6,406,921 B1) (June 18, 2002) further in view of Wang et al. (U.S. Patent 5,922,617) (July 13, 1999).

Schultz in view of Wagner et al. teach a method of claims 7, 48-65 and 88-91 as described above.

Schultz in view of Wagner et al. do not teach a method further comprising recording results of the detecting in a database and clustering the records to identify addresses which are related.

Wang et al. teach a method further comprising recording results of the detecting in a database and clustering the records to identify addresses which are related (Figures 1-11 and Column 17, lines 12-47).

Schultz in view of Wagner et al. do not teach a method further comprising making the results of the evaluating accessible to a network of health care providers and physician.

Wang et al. teach a method further comprising making the results of the evaluating accessible to a network of health care providers and physician (Column 17, lines 56-67).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method further comprising recording results of the detecting in a database and clustering the records to identify addresses which are related of Wang et al. in the method of Schultz in view of Wagner et al. since Wang et al. states, "Each of the stages in the process requires a high degree of accuracy and efficiency to ensure that the signal is not obscured by noise and that one has an efficient and rapid method for screening

large numbers of samples and reagents (Column 1, lines 58-64)". An ordinary practitioner would have been motivated to combine and substitute the method further comprising recording results of the detecting in a database and clustering the records to identify addresses which are related of Wang et al. in the method of Schultz in view of Wagner et al., in order to achieve the express advantages, as noted by Wang et al., of an invention, which specifically provides a high degree of accuracy and efficiency to ensure that the signal is not obscured by noise and that one has an efficient and rapid method for screening large numbers of samples and reagents.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

Art Unit: 1634

November 12, 2003 ARUN K. CHAKRABARTI
PATENT EXAMINER

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